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Ronald P. Ryan
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Re: Patent Term Extension
Application for
U.S. Patent No. 4,338,317

#14

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,338,317 issued July 6, 1982, which claims the human drug product SERZONE, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be two years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of April 24, 1995. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase} \\ &= \frac{1}{2} (3,216) + 1,204 \\ &= 2,812 \text{ days}\end{aligned}$$

Since the regulatory review period began after the patent issue date, the entire period has been considered. No determination of a lack of due diligence was made.

The two year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because: (1) the patent was issued before the date of enactment (September 24, 1984) of 35 U.S.C. § 156; (2) the date of exemption under subsection 505(i) of the Federal Food, Drug and Cosmetic Act involving the approved product became effective (November 17, 1982) was before the date of enactment; and, (3) the date of the new drug application was approved (December 22, 1994) was after the date of enactment. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed two years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for two years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of two years.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,338,317
Granted: July 6, 1982
Applicant: Davis L. Temple, Jr. et al.
Owner of Record: Mead Johnson & Company
Title: PHENOXYETHYL-1,2,4,-TRIAZOL-3-ONE
ANTIDEPRESSANTS
Classification: 514/255
Product Trade Name: SERZONE
Term Extended: two years

Gerald A. Dost
Gerald A. Dost
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: SERZONE
FDA Docket No.: 95E-0038